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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,057	02/05/2001	Colin Brown	9052-67	1282

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EXAMINER	
WHITE, EVERETT NMN	

ART UNIT	PAPER NUMBER
1623	8

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/700,057	BROWN, COLIN	
	Examiner	Art Unit	
	EVERETT WHITE	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35,37 and 39-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35,37 and 39-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The Amendment B filed October 3, 2002 has been received, entered into the record into the record and carefully considered. The following information provided in the amendment affects the instant application by:

A) The amendment provides replacement paragraphs at page 1, line 21-page 2, line 3. The amendment adds no new matter and has been entered.
B) Claims 36 and 38 have been canceled.
C) Claims 22 and 23 have been amended.
D) Claims 40-43 are newly added.
E) Remarks drawn to
   I. 112 Second Paragraph rejection, rendered moot by amendment and cancellation of the claims.
   II. Claims Objections, rendered moot since Claim 38 has been canceled.
   III. Claims Rejection Under 103
   Sections A, B, C and D

2. An action on the merits of Claims 1-35, 37, 39 and newly added Claims 40-43 And responses to the 35 U.S.C. 103 arguments indicating the examiner has erred in asserting a prima facie case of obviousness are contained herein below.

3. The text of those sections of title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112, 2nd Paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 6-9, 13, 29 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, lines 1 and 2, in the phrase "adhesions in or associated with a body cavity", what does "associated with a body cavity mean"?

Claims 6-9 fail to disclose the unit of molecular weight measurement, which renders claims indefinite.

Claims 13 and 29 set forth terms in parentheses, which is improper and render the claims indefinite.

Claim 40 appears to be incomplete. The phrase "prevention of adhesions" at lines 2 and 3 of Claim 40 should be changed to (for example) -- prevention of adhesions of tissue-- or – prevention of adhesions of organs— , whatever is appropriate in order to make the claim complete.

Claim Rejections - 35 USC § 112, 1st Paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-35, 37 and 39-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing the incidence of adhesion of tissues in or associated with a body cavity, does not reasonably provide enablement for preventing the incidence of adhesions of tissues in or associated with a body cavity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicants claim a method of preventing or reducing the incidence of adhesions in or associated with a body cavity, comprising introducing into the body cavity a composition comprising an aqueous formulation further comprising a polysaccharide dextrin in an amount effective to prevent or reduce the incidence of such adhesions, wherein the dextrin comprises more than 15% of polymers with a degree of polymerization (DP) greater than 12 and acts as an osmotic agent to maintain a volume of the aqueous formulation in the body cavity serving to separate tissues which otherwise may adhere to each other.

Undue experimentation is a conclusion reached by weighing the noted factural considerations set forth below in *In re Wands*, 858 F.2d 731, USPQ 2d 1400 (Fed. Circ. 1988). A conclusion of lack of enablement means that, based on the evidence

regarding a fair evaluation of an appropriate combination of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

The *In re Wands* factors include:

(1) The quantity of experimentation necessary (time and expense);

(2) The amount of direction or guidance presented;

(3) The presence or absence of working examples of the invention;

(4) The nature of the invention;

(5) The state of the prior art;

(6) The relative skill of those in the art;

(7) The predictability or unpredictability of the art; and

(8) The breadth of the claims.

With regard to factors (1) and (2) cited above, the quantity of experimentation needed to determine the amount of the composition, the time table necessary to achieve efficacious administration, dosage frequency as well as specific identity of the type of operations and conditions for which the invention is applicable (i.e. will be effective for reducing or preventing) has not been provided adequate guidance in the written description for accomplishing and determining such. The example disclosed in the instant specification only demonstrates the effectiveness of the composition to reduce the incidence of post-operative adhesion formation. However, reduction does not equal prevention.

With regard to factors (4), (5) and (7), it is noted that there is a great deal of unpredictability of efficacy for preventing the incidence of adhesions of tissues in or associated with a body cavity. The instant specification fails to provide a specific methodological procedure for which the instant method can or is intended to prevent the incidence of adhesions of tissue and it fails to mention any specific operation or condition that the composition was effective in preventing the incidence of adhesion of tissue in or associated with a body cavity. The art at the time the invention was made fails to establish predictiability with regard to the efficacy of the composition in

preventing the incidence of adhesions of tissues in or associated with a body cavity as instantly claimed.

With regard to factors (3) and (8), it is noted that while there is a working example of the effectiveness of a composition to reduce the incidence of post-operative adhesion formation in the specification, it is not seen as sufficient to support the breath of the claims, wherein the scope of the claims encompasses a method of preventing the incidence of adhesions of tissues in or associated with a body cavity. It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves. See In re Gardner et al. 166 USPQ 138 (CCPA 1970). Therefore, in view of the unpredictability in the art, the lack of working examples, and the lack of guidance in how the skill artisan would use the composition to prevent the incidence of adhesion of tissue in or associated with a body cavity, it would require an undue amount of experimentation to practice the claimed invention which encompasses preventing the incidence of adhesion in or associated with a body cavity of all types of conditions and operations in scope with the instantly claimed invention.

7. Applicant's arguments with respect to Claims 1-35, 37 and 39-43 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

8. Claims 1, 2, 4-10, 12, 13, 17, 18, 22 and newly added Claims 40-43 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Davies (US Patent No. 5,258,175) for the reasons already of record on page 3 of the Office Action mailed May 21, 2002.

9. Applicant's arguments filed October 3, 2002 have been fully considered but they are not persuasive. Applicants argue that the Davies patent fails to establish a prima facie case of obviousness because Davies proposes a dextrin derivative wherein a proportion of the hydroxyl groups in the dextrin derivative have been replaced by strongly acidic groups. This argument is not persuasive since instant Claim 12 sets forth a composition that comprises dextrin, which is substituted by one or more different

groups, which include neutral groups, which embraces the acidic groups of the Davies patent. Applicant's argument with regard to the use of dextrin sulphate by the Davies patent is also not persuasive since instant Claim 12 also indicates that the dextrin thereof may be substituted with a sulphate group.

Applicant also appears to argue against the rejection of the claims over the Davies patent on the basis of how the use of the dextrin in the instant claims is different from the utility of the dextrin in the Davies patent. In response to applicant's argument that one of ordinary skill in the art would not be motivated to use the proposed dextrin derivative of the Davies patent as a composition useful for preventing or reducing the incidence of adhesions in or associated with a body cavity as recited in Claim 1 because Davies proposed a dextrin derivative formulated for the treatment of poisoning or drug overdoes, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Accordingly, the rejection of Claims 1, 2, 4-10, 12, 13, 17, 18, 22 and newly added Claims 40-43 under 35 U.S.C. 103(a) as being unpatentable over the Davies patent is maintained for the reasons of record.

10. Claims 1-19, 21, 22, 37, 39 and newly added Claims 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Viegas et al (US Patent No. 5,587,175, already of record) in view of Davies (US Patent No. 5,258,175, already of record).

Viegas et al discloses aqueous pharmaceutical vehicles comprising a film forming polymer and an ionic polysaccharide that can be gelled. The film forming polymer may be represented as polydextrin, sodium hyaluronate, chondroitin sulfate which embraces the presence of a polysaccharide dextrin, hyaluronate, and a glycosaminoglycan in a composition as set forth in instant Claims 1, 11, 21 and 22. The Viegas et al patent discloses that the composition contain about 1% to about 50% by weight of the film forming polymer, which covers the amount of dextrin disclosed in

instant Claims 14-16 when the film forming polymer of the Viegas et al patent is represented as polydextrin. The instant claims differ from the Viegas patent by claiming that the composition is for preventing or reducing the incidence of adhesions in or associated with a body cavity. Applicants are reminded that the difference in intended use cannot render a known composition novel.

The instant claims also differ from the Viegas et al patent by claiming that the dextrin contains more than 15% of polmers with a degree of polymerization greater than 12. The Davies patent discloses a dextrin derivative that is derived from a dextrin which is a glucose polymer mixture containing at least 15%, preferably at least 50%, by weight of glucose polymers of D.P. (degree of polymerization) greater than 12. Davies discloses the dextrin as having a weight average molecular weight of from 15,000 to 25,000 (see column 2, paragraphs 1 and 2), which fall within the weight average molecular weight range disclosed in instant Claims 8 and 9. Davies also discloses the use of dextrin sulphate as the dextrin derivative (see column 2, line 11), which encompassed the subject matter of instant Claims 12 and 13. The Davies patent further discloses the present of electrolytes in a dextrin sulphate composition that may be selected as calcium or sodium (see the table in column 3, line 10), which embraces the subject matter of instant Claims 17 and 18. The examples set forth solutions of a dextrin sulphate composition that embraces the subject matter of instant Claim 2.

One would be motivated to combine the teachings of the Viegas et al and Davies patents in a rejection of the instant claims since both patents disclose dextrin compositions that have medical applications. See the abstract of the Viegas et al patent where hyper-osmotic, hypoosmotic, or isoosmotic gels (which may be selected as polydextrin gels) are suited for topical body cavity or injection application of drugs or diagnostic agents. See column 1, 2nd paragraph of the Davies patent wherein it is suggested that it is well known in the art that dextrin, as an osmotic agent, consisting of a glucose polymer mixture containing at least 15% by weight of glucose polymers of D.P. greater than 12 can be introduced into the abdominal cavity of a patient to effect peritoneal dialysis.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the polydextrin that may be administered to the body cavity of a patient as a diagnostic agent in the Viegas et al patent with a dextrin consisting of a glucose polymer mixture containing at least 15% by weight of glucose polymers of D.P. greater than 12 in view of the recognition in the art, as evidenced by the Davies patent, that dextrin consisting of a glucose polymer mixture containing at least 15% by weight of glucose polymers of D.P. greater than 12 is effective as an osmotic agent for introduction into a body cavity of a patient.

11. Applicant's arguments with respect to Claims 1-19, 21, 22, 37, 39 and newly added Claims 40-43 have been considered but are moot in view of the new ground(s) of rejection.

12. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Viegas et al patent in view of the Davies patent as applied to Claims 1-19, 21, 22, 37, 39 and new added Claims 40-43 above, and further in view of Apfeld et al (US Patent No. 5,230,933, already of record).

The information disclosed in the above rejection of the claims over the Viegas et al patent in view of the Davies patent is applied in the current rejection of Claims 19 and 20. The composition of the instant invention differs from the composition of the Viegas et al and Davies patent by claiming the presence of a lubricant in the composition.

Apfeld et al discloses a composition comprising a cellulose ether, dextrin and lecithin (see abstract) whereby the lecithin is a mixture of naturally occurring phospholipids (see column 9, lines 55 and 56). See column 9, lines 64 and 65 of the Apfeld et al patent whereby the text indicates that lecithin is known to function as a lubricant.

One is motivated to combine the teachings of the Viegas et al and Davies patents with the Apfeld et al patent in a rejection of the claims since each patent discloses dextrin composition formulations.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the dextrin composition of the Viegas et al and

Davies patents to include lubricants in view of the recognition in the art, as evidenced by Apfeld et al patent, that lecithin as a mixture of naturally occurring phospholipids is effective as a lubricant for food grade applications.

13. Applicant's arguments with respect to Claims 19 and 20 have been considered but are moot in view of the new ground(s) of rejection.

14. Claims 23-35 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Viegas et al (US Patent No. 5,587,175) in view of Milner (US Patent No. 4,886,789) for the reasons already of record.

15. Applicant's arguments filed October 3, 2002 have been fully considered but they are not persuasive. Applicants argue that the Viegas et al patent does not disclose a composition comprising an aqueous formulation containing the polysaccharide dextrin wherein the dextrin contains more than 15% of polymers with a degree of polymerization (DP) greater than 12. This argument is not persuasive since the instant rejection is over the combination of the Viegas et al and Milner patents. See column 6, lines 13-50 where the Milner patent discloses a glucose polymer mixture comprising more than 15% by weight of glucose polymers having a degree of polymerization of more than 12. The description of the glucose polymer indicates hydrolysis of dextrinized starch, which suggests that the glucose polymer described by Milner is dextrin, which embraces the polysaccharide dextrin indicated in instant Claim 23. Applicants argue that the Milner patent does not recite a composition for preventing or reducing the incidence of adhesion in or associated with a body cavity. This argument is not persuasive since the rejection of the claims is based on the combination of the Viegas et al and Milner patents. The abstract of the Viegas et al patent discusses compositions suited for topical body cavity and compositions for separating surgically or injured tissue as a means of preventing adhesions. Applicants further point out the difference in the length of treatment between the Milner patent and the instant claims on page 12, 2nd paragraph of Applicants response. However, this argument is not persuasive because an extended length of time for maintaining dextrin in the body cavity in order to obtain a particular result is within the skill of the artisan in this art.

Accordingly, the rejection of Claims 23-35 under 35 U.S.C. 103(a) as being unpatentable over the Viegas et al in view of the Milner is maintained for the reasons of record.

Summary

16. Claims 1-35, 37 and 39-43 are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

17. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit out website at **www.uspto.gov** and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reach on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. White
E.White

James O. Wilson
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